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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,715	11/12/2003	John I. Shipp	127.0005-00000	7246
<div>22882 7590 12/12/2007</div> <div>MARTIN & FERRARO, LLP</div> <div>1557 LAKE O'PINES STREET, NE</div> <div>HARTVILLE, OH 44632</div>				
			<div>EXAMINER</div> <div>SONNETT, KATHLEEN C</div>	
			<div>ART UNIT</div> <div>3731</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>12/12/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,715	Applicant(s) SHIPP, JOHN I.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

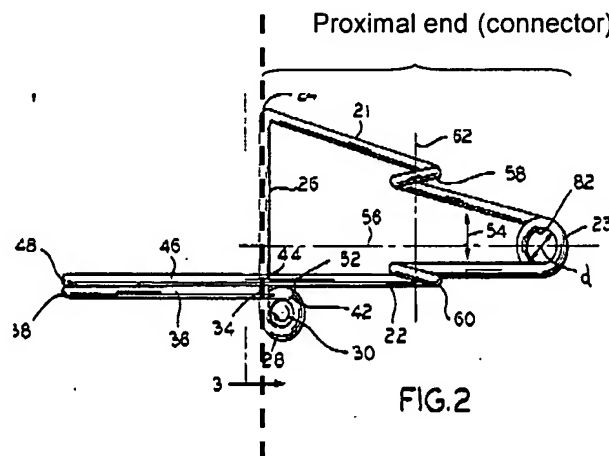
Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/14/2007 have been fully considered but they are not persuasive.
2. Regarding Perlin (US 4,777,949), Sigler (US 1,666,514), and Kees Jr. (US 4,777,950), applicant argues that these references fail to disclose free ends that terminate proximate the proximal end. The connector of the clip is claimed as being at the proximal end of the clip. Taking fig. 2 of the device of Perlin as an example, the connector is labeled below. This entire region can be considered the proximal end of the clip since it includes the connector and the free ends of the wire are proximate this region (near dotted line).



3. This has been similarly applied to the devices of Kees, Jr. and Sigler. The entire proximal half of the device can be considered the proximal end.
4. Applicant also argues that the devices of Perlin, Kees, Jr., Parker (US 3,125,789), and Larson (U.S. 2,113,991) fail to disclose support members wherein at least one of the upper and lower support member has a width in a second plane that is greater than the width of the

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connector taken in a first plane, the planes generally parallel to each other and to the mid-longitudinal axis. However, the width of the connector or support member can be taken in any plane parallel to the mid-longitudinal axis. There is no language in the claim indicating that the width being looked at must correspond to a maximum width of the connector. Again looking at Perlin for example, the width of the connector is less than the width of the upper and lower support member if the width of the connector is looked at in a plane that contains only a single "pass" of the wire (no loop or coil; only as wide as section 24 in fig. 3). The width of the upper and lower support member contains two wire "passes" and a gap. The widths of the other prior art devices have been explained in the art rejections.

5. The objections to the specification and claim 2 have been withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

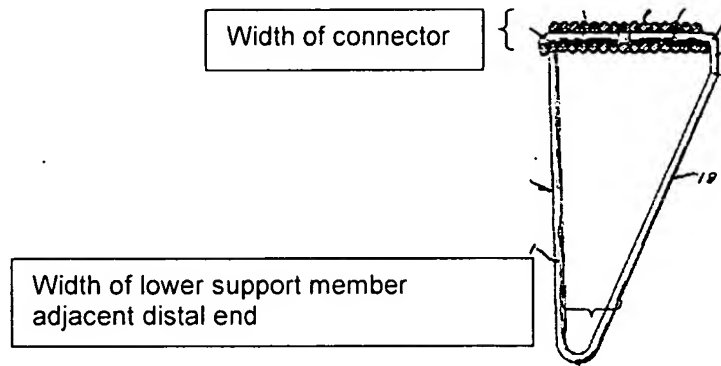
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1, 3-7, 12, 13, 15-20, 28, and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Parker (U.S. 3,125,789). Parker discloses a clip capable of ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, a distal and proximal end, and a length between the ends, an upper support member (27,29) oriented generally along the mid-longitudinal axis and a lower support member (19,21) oriented generally along the mid-longitudinal axis of the clip and a connector (10) at the proximal end of the clip, the connector joining the upper and lower support members, the clip being formed of a single piece of wire (col. 1 ll. 44-47) having a first and second free end (15 and 33), each terminating proximate the

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proximal end (see fig. 3). At least one of the upper and lower support members has a width in a second plane that is greater than the width of the connector in a first plane, the two planes generally parallel to each other. The widths can be considered the dimensions shown below:



8. Regarding claims 12 and 13, Parker discloses a clip comprising a mid-longitudinal axis a distal and proximal end and a length between ends, an upper support member and lower support member both being oriented generally along the mid-longitudinal axis of the clip between the ends of the clip and a connector. The lower support member is opposite the upper support member in a vertical plane parallel to the mid-longitudinal axis. Looking at the coil in figs 1 or 3, element (11) of the lower support member starts to form the coil member. The first half of the coil (starting at (21,22)) is being considered part of the lower support member and the second half (which eventually becomes pieces (25,26,27)) is being considered part of the upper support member. Parker discloses a connector at the proximal end of the clip that joins the upper and lower support members, the clip being formed of a single piece of material having a first and second free end terminating proximate the proximal end. At least one of the free ends faces in a direction that is transverse to the mid-longitudinal axis of the clip (see fig. 3). See the figure above regarding the width dimensions of the support members and connector.

9. Regarding claim 15, the ends (15, 33) face a direction generally transverse to the mid-longitudinal axis of the clip. This is considered away from the proximal end of the clip. That is, away from the proximal end does not necessarily mean towards the distal end, rather any direction besides toward the proximal end.

10. Regarding claims 3 and 16, see col. 2 ll. 54-57 (opening against the force of the connector).

11. Regarding claims 4 and 17, the clip is a coiled torsion spring clip and is adapted to clip onto objects.

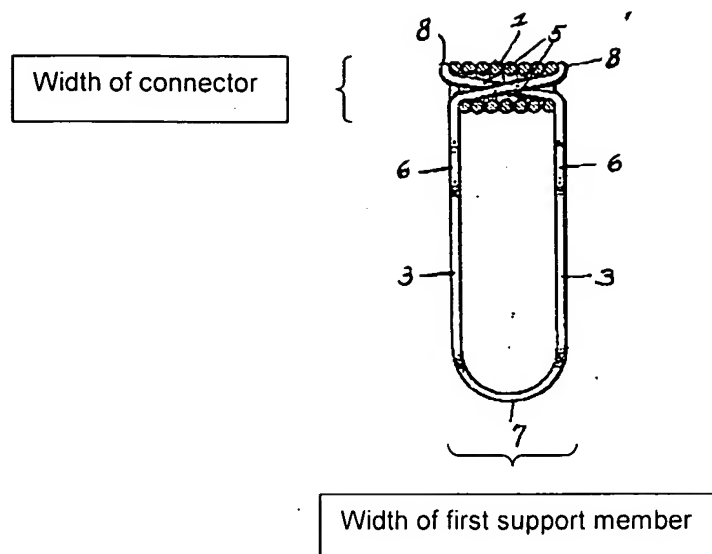
12. Regarding claims 5, 6, 18, and 19, the connector includes a coil having an interior, the first and second ends of the wire terminating proximate the interior of the coil (see fig.3).

13. Regarding claims 7 and 20, see (20) and (28).

14. Regarding claims 28 and 32, each support member is formed of first and second legs.

15. **Claims 1, 3-9, 12, 13, 16-22, 28, 29, 32, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Larsen (U.S. 2,113,991). Larsen discloses a clip capable of ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, a distal and proximal end, and a length between the ends, an upper support member oriented generally along the mid-longitudinal axis and a lower support member oriented generally along the mid-longitudinal axis of the clip and a connector (1) at the proximal end of the clip, the connector joining the upper and lower support members, the clip being formed of a single piece of wire (col. 1 ll. 38-41) having a first and second free end (5, 8), each terminating proximate the proximal end (see fig. 3). The width of the support members in a second plane is greater than the width of the connector in a first plane, the planes being generally parallel to the mid-longitudinal axis and each other.

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16. Regarding claims 12 and 13, Larsen discloses a clip comprising a mid-longitudinal axis a distal and proximal end and a length between ends, an upper support member and lower support member both being oriented generally along the mid-longitudinal axis of the clip between the ends of the clip and a connector. The lower support member is opposite the upper support member in a vertical plane parallel to the mid-longitudinal axis. For example, looking at the coil, the lower support member starts to form the coil member. The first half of the coil is being considered part of the lower support member and the second half is being considered part of the upper support member since it leads into it. Larsen discloses a connector at the proximal end of the clip that joins the upper and lower support members, the clip being formed of a single piece of material having a first and second free end terminating proximate the proximal end. The two ends face in a direction that is generally transverse to the longitudinal axis of the clip. The ends are being considered elements 5 and 8. Although the ends (5) turn up at their very ends, the majority of the ends (5) face in a direction that is transverse to the mid-longitudinal axis of the clip.

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17. Regarding claims 3 and 16, see col. 2 ll. 54-57 (opening against the force of the connector).

18. Regarding claims 4 and 17, the clip is a spring clip.

19. Regarding claims 5, 6, 18, and 19, the connector includes a coil having an interior, the first and second ends of the wire terminating proximate the interior of the coil (see fig.3).

20. Regarding claims 7 and 20, see (20) and (28).

21. Regarding claims 8, 9, 21 and 22, the upper and lower support members each have two parallel longitudinal members with a recess therebetween, the members of the upper support member being adapted to generally overlie the longitudinal members of the lower support member.

22. Regarding claims 28, 29, 32, and 33, each of the upper and lower support members are formed of first and second generally parallel legs extending from the connector.

23. **Claims 1, 12, 14, 27, 28, 31, and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Sigler (U.S. 1,666,514). Sigler discloses a clip capable of ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, a distal and proximal end, and a length between the ends, an upper support member (6) oriented generally along the mid-longitudinal axis and a lower support member (2) oriented generally along the mid-longitudinal axis of the clip and a connector (4) at the proximal end of the clip, the connector joining the upper and lower support members, the clip being formed of a single piece of wire having a first and second free end (1,10), each terminating proximate the proximal end (see fig. 1). As discussed above, the entire proximal half can be considered the proximal end. The width of the support member (6) is larger than the width of the connector (4).

24. Regarding claims 12 and 14, the lower support member is opposite the upper support member in a vertical plane parallel to the mid-longitudinal axis. For example, looking at fig. 1,

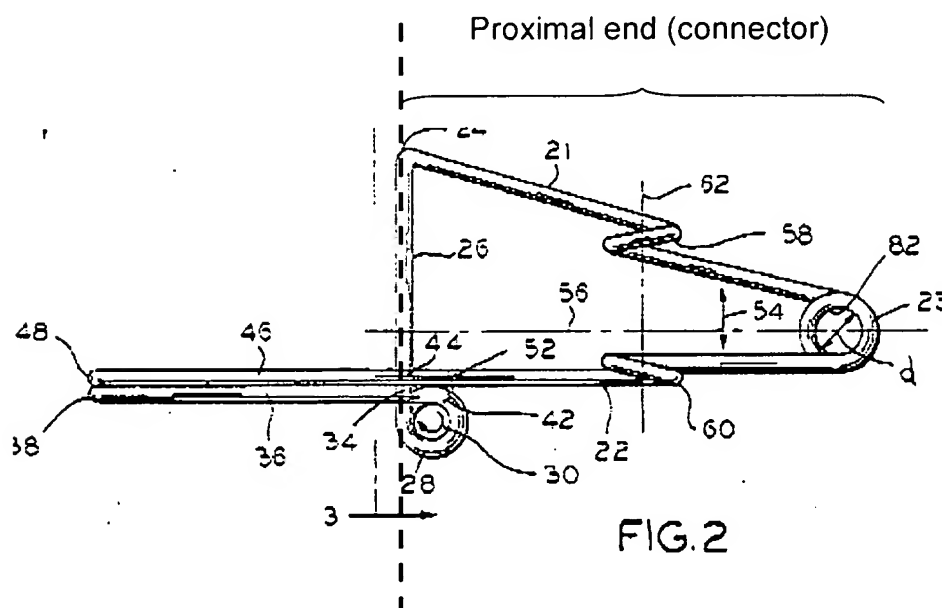
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paper 11 defines a vertical plane and the support members are on opposite sides of the plane.

The free end (10) faces generally toward the distal end of the clip.

25. Regarding claims 27, 28, 31, and 32, the support members comprise first and second leg members and at least one of the upper and lower support member is enlarged adjacent the distal end of the clip since both flare out toward the distal end.

26. **Claims 1, 3-10, and 27-30** are rejected under 35 U.S.C. 102(b) as being anticipated by Perlin (U.S. 4,777,949). Perlin discloses a clip capable of ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, a distal and proximal end, and a length between the ends, an upper support member (46) oriented generally along the mid-longitudinal axis and a lower support member (36) oriented generally along the mid-longitudinal axis of the clip and a connector at the proximal end of the clip, the connector joining the upper and lower support members, the clip being formed of a single piece of wire (col. 2, ll. 51-54) having a first and second free end (42,52), each terminating proximate the proximal end (see figure below).



27. Since the connector is at the proximal end, the entire region designated above as the connector is considered the proximal end and the free ends of the wire are proximate this region. The width of the connector is less than the width of the upper and lower support member if the width of the connector is looked at in a plane that contains only a single "pass" of the wire (no loop or coil). The width of the upper and lower support member contains two wire "passes" and a gap.

28. Regarding claims 3 and 4, the connector is adapted to bias the upper and lower support member toward one another. The connector applies a force to the support members that is greater than that needed to move the members into contact with one another as seen in fig. 7 and 8, where the support members are able to flatten the vessel (V) and the clip is spring biased closed.

29. Regarding claims 5 and 6, the connector includes a coil (28) having an interior. The ends are proximate the coil.

30. Regarding claim 7, see (38) and (48).

31. Regarding claims 8 and 9, see fig. 9.

32. Regarding claim 10, see fig. 7 and 8, especially elements (70) and (72).

33. Regarding claims 27-30, each of the upper support member and the lower support member is formed of a first and second leg extending generally parallel to one another from the connector. There is a gap formed between the legs, the gap having a width approximately equal to the diameter of the wire (see fig. 3, 9).

34. **Claims 1, 3, 4-7, 10, 12, 13, 15-20, 23, 28, 29, 32, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Kees, Jr. (U.S. 4,777,950). Kees discloses a clip capable of ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, a distal and proximal end, and a length between the ends, an upper support member oriented generally

along the mid-longitudinal axis and a lower support member oriented generally along the mid-longitudinal axis of the clip and a connector (34, 38, 40) at the proximal end of the clip, the connector joining the upper and lower support members, the clip being formed of a single piece of wire having a first and second free end, each terminating proximate the proximal end (see fig. 1). The width of the lower or upper support member adjacent the distal end is greater than the width of the connector if the width of the connector is considered in a plane that only includes one piece of wire. The width of the upper or lower support member includes two wire "passes" at the distal end.

35. Regarding claims 12, 13, and 15, the lower support member is opposite the upper support member in a vertical plane parallel to the mid-longitudinal axis. The examiner is considering portion (44) to be part of the lower support member since it connects to the lower support member in fig. 2 and portion (42) to be part of the upper support member. These portions are opposite each other on either side of a vertical plane (see fig.3). The ends (32, 30) face a direction generally transverse to the mid-longitudinal axis of the clip. This is considered away from the proximal end of the clip. That is, away from the proximal end does not necessarily mean towards the distal end, rather any direction besides toward the proximal end.

36. Regarding claims 4 and 17, the clip is used to seal off an aneurysm (col. 2 ll. 31-33) and is a spring clip.

37. Regarding claims 5, 6, 18, and 19, the connector includes a coil (34). This coil has an interior because the free ends of the clip are proximate the coil, they are proximate of every portion of the coil including the interior of the coil.

38. Regarding claims 7 and 20, see fig. 1.

39. Regarding claim 10, see col. 2, ll. 26-34.

40. Regarding claims 28, 29, 32, and 33, each support member comprises first and second legs extending generally parallel to one another from the connector.

Claim Rejections - 35 USC § 103

41. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

42. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Perlin in view of Shipp et al. (U.S. 5,593,414). Perlin discloses the invention substantially above including that the clip is only a few millimeters in maximum dimension but is silent on the diameter of the wire.

43. However, Shipp et al. discloses that it is old and well known to use a wire having a diameter of 0.75mm to form a surgical clip. This small diameter allows the clip to be placed within an endoscopic surgical field through a 5 mm diameter trocar port. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Perlin to use a 0.75 mm diameter wire as made obvious by Shipp et al. in order to gain the advantage of being able to introduce the clip through a very small diameter trocar port.

44. **Claims 11 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees, Jr. in view of Shipp et al. (U.S. 5,858,018). Kees discloses the invention substantially as stated above including that the clip may be applied using a clip applier, but does not disclose using a clip applier that includes a magazine adapted to hold a plurality of clips.

45. However, Shipp discloses a surgical clip applier that avoids permanently deforming or weakening spring clips. The applier includes a cartridge (see fig. 2). Such cartridges are advantageous because they allow a plurality of clips to be delivered without having to remove or

reload the device after a clip is delivered. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Kees, Jr. to include a clip applier in combination with the clip that includes a magazine adapted to hold a plurality of clips as made obvious by Shipp in order to be able to deliver a plurality of clips without having to remove and reload the device after each clip is delivered.

46. **Claims 12 and 32-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Perlin in view of Kees, Jr. Perlin discloses a surgical clip for ligating a fluid carrying structure, the clip comprising a mid-longitudinal axis, upper and lower support members and a connector at the proximal end of the clip having a width in a first plane, at least one of the upper and lower support members having a width in a second plane generally parallel to the first plane that is less than the width of the connector as discussed in more detail above. The clip has free ends terminating proximate the proximal end (connector) and each support member comprises first and second legs extending generally parallel to one another from the connector with a gap between the first and second legs, the gap being approximately as wide as the diameter of the wire. Perlin fails to disclose that at least one of the free ends faces a direction that is away from the proximal end of the clip.

However, Kees teaches bending the free ends of a wire surgical ligating clip away from the proximal end of a clip, the proximal end of the clip comprising a connector. Kees teaches that the bends (30 and 32) preclude the support member contacting portions from advancing beyond their contact plane when misaligned into non-opposed relation and therefore maintain alignment between jaws even if the jaws are mispositioned (col. 1, ll. 10-18, 31-33). It would have been obvious to one skilled in the art to modify the device of Perlin to face the free ends of the wire away from the proximal end of the clip in order to form horns as taught by Kees, the horns helping to maintain alignment of the support members.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 11/14/2007


GLENN K. DAWSON
PRIMARY EXAMINER